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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/817,064

04/02/2004

Richard H. Sandler

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2687

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7590

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EXAMINER

NASSER, ROBERT L

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

01/08/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/817,064	<b>Applicant(s)</b> SANDLER ET AL.	
	<b>Examiner</b> ROBERT L. NASSER	<b>Art Unit</b> 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 3735

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 32, and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. These claims recite optimizing the frequency band. While the specification supports this feature, it is unclear how the steps disclose actually optimize the band. Clarification is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5, 6, 11, 15, 17-19, 21, 22, 27, 31, 33-35, 37, 38, 43, and 47 are rejected under 35 U.S.C. 102(b) as being anticipated by Chassaing et al 6278890. Chassaing teaches in figures 30-23 and the discussion starting in column 9, at line 27, under the heading, "Non-invasive detection of change in coronary artery stenosis," a method including the steps of receiving sound information from blood in flowing in a vascular structure, converting the sound into data associated with individual cardiac cycles over a plurality of cardiac

Art Unit: 3735

cycles (see column 31, lines 30-35), processing the data to produce an acoustic characteristic indicative of a current state of a vascular condition, i.e. post intervention, and detecting a change in the condition by computing the difference between the current state on the characteristic at a pre-intervention time (see columns 29-34). Claim 2 is rejected in that the method detects a change in the amount of stenosis. Claim 3 is rejected in that the difference between pre and post intervention data is used to determine a change in vascular diameter. Claim 5 is rejected in that Chassaing uses spectral data as the characteristic and determines the difference between the spectral data (see column 32, lines 25+). Claim 6 is rejected in that the data is averaged (column 32, line 44). Claim 11 is rejected in that Chassaing uses multiple sensors. Claim 15 is rejected in that Chassaing selects low and high frequency bands (see column 35). Claims 17-19, 21, 22, 27, 31, 33-35, 37, 38, 43, and 47 are rejected in that Chassaing is a computer implemented method. Hence, it has the system and memory with a program to perform the method.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-11, 17-21, 23-27, 33-37, and 39-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shertukde et al 7291111 in view of Chassaing. Shertukde et al diagnoses coronary artery disease by taking the

Art Unit: 3735

wavelet transformation of an acoustic signal, which has been divided into individual heartbeat data, so as to identify the diastolic portion thereof. It does not detect a change in the artery disease by comparing two different measurements. However, Chassaing teaches that by monitoring over time, a method like that of Shertukde can be used to determine changes in the condition, such as pre and post angioplasty, In order to ensure that the patient receives proper care. Hence, it would have been obvious to modify Shertukde to repeat measurements to identify a change in the condition, to improve the overall care of the patient. Claims 2 and 3 are rejected in that the combination monitors changes a stenotic vessel, which monitors diameter changes. With respect to claim 4 would have been obvious for one skilled in the art to set a threshold to indicate a clinically significant change, as opposed to just and slight variation, to ensure that the intervention procedure is not falsely indicated to be successful. Claim 5 is rejected in that a wavelet transform includes spectral data. Claim 7 is rejected in that the exact measure of the difference would have been a mere matter of design choice for one skilled in the art. Claims 8 and 10 are rejected in that a wavelet transformation also includes temporal data, as it include time and frequency information. The data includes envelope data. Claim 9 is rejected in that the exact measure of the difference would have been a mere matter of design choice for one skilled in the art. Claims 17-21, 23-27, 33-37, and 39-43 are rejected for the reasons given above, noting that Shertukde is a computer implemented method.

Art Unit: 3735

Claims 4, 7, 20, 23, 36, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chassaing. With respect to claims 4, 20, and 36, it would have been obvious for one skilled in the art to set a threshold to indicate a clinically significant change, as opposed to just and slight variation, to ensure that the intervention procedure is not falsely indicated to be successful. Claims 7, 23, and 39 are rejected in that the exact measure of the difference would have been a mere matter of design choice for one skilled in the art.

Claims 12-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chassaing et al in view of Kynor 5311867. Chassaing groups the data into individual heartbeat data, but does not do so using a template. Kynor teaches grouping incoming data into beat data based on cross correlation with a template. Hence, it would have been obvious to modify Chassaing to use such a template matching method, as it is merely the substitution of one known separation method for another. Claim 14 is rejected in that cross correlation includes determining the differences between the template and the data.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Crutchfield et al 6692443, Akay et al 5638823, and Semmlow 5036857 show similar devices that identify artery disease from acoustic information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT L. NASSER whose telephone number is (571)272-4731. The examiner can normally be reached on m-f 9-5.

Art Unit: 3735

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/  
Primary Examiner  
Art Unit 3735

RLN  
January 7, 2008

Art Unit: 3735